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Pharmaceutical Patent law and licensing

18 September 2006

Kiran BHUPATHIRAJU, Chief Executive
Laila Research Centre
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BY ELECTRONIC MAIL

Re: United States Patent No. 6,160,172
United States Patent No. 6,395,296
Indfrag Ltd. multiple-salt Hydroxycitric acid product

Dear Kiran :

Many thanks for taking the time to meet with me today to discuss Indfrag. I understand we have two independent but related issues: Indfrag's current sales of potentially-infringing product in the U.S.A., and Indfrag's potential future U.S. patent on 3-, 4- and 5-salts of hydroxycitric acid (HCA).

Current Infringement

Regarding current infringement, for us to commence a case to stop this, I will need to trouble you for a few things:

- 1) A copy of the license contract between Vittal Mallya and Leila for the captioned patents.
- 2) Copies (either hard copies or scanned Adobe® acrobat files are acceptable) of any papers relating to prior litigation involving these patents in India or elsewhere.
- 3) Correspondence from Indfrag describing its product;
- 4) Indfrag advertising describing its product;
- 5) Certificate(s) of Analysis from Indfrag describing its product

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- 6) Statements by Indfrag to government regulatory or patent offices describing its product (I understand from our meeting that at some point, Indfrag actually said that it recognizes that its product contains 2-salts);
- 7) An independent chemical analysis of the Indfrag product;
- 8) A scientific analysis of the thermodynamics of this class of salts, showing the theoretical relative molar concentrations of each salt (1-, 2-, 3-, 4- and 5-salts) in a mixture. For example, with a sodium 1-salt, I assume that one can calculate the thermodynamic equilibrium constant for HCA, and for NaHCA, and for Na₂HCA, and for Na₃HCA. Given these equilibria, and given temperature and humidity conditions, I assume that one can calculate what percent of the total number of moles of HCA should be present as HCA, and as NaHCA, and as Na₂HCA, and as Na₃HCA. I assume that we can do the same thing for 2-salts, and 5-salts. I assume a lot, but I am a rather good lawyer and a rather poor chemist; am I correct here?
- 9) Any other evidence showing what Indfrag's product is.
- 10) Information enabling us to physically locate Indfrag's product as it enters The United States (e.g., India customs / export filings).
- 11) Information on Laila's sales of HCA in The United States of America before the spring of 2002, showing (a) what was sold (e.g., a Certificate of Analysis) and (b) when it was sold.
- 12) The contact information for Indfrag's USA distributor (from whom I can request a product sample).

As you send me these materials, we can review them and decide when we have compiled enough evidence to file a lawsuit.

Potential Future Patent

I have to complement you on an exceptionally thorough knowledge of the prior art; it is rare that I have the pleasure of working with a client who comes to me with relevant prior art already in-hand.

As we discussed, we have several ways to bring this information to the attention of the Patent Office: (1) immediately, via informal correspondence to Indfrag's U.S. patent attorneys; (2) immediately, via informal correspondence to the patent Examiner; and (3) after the patent issues, via a formal proceeding(s) to suspend and revoke Indfrag's patent. As informal approaches have a high risk of failure, and because that failure may prejudice an otherwise-meritorious formal patent challenge, I recommend option (3). While we cannot file this until the patent issues, we can prepare it in advance, so that it is ready to file literally on the same day that the patent issues. This would enable the Patent Office to issue a preliminary invalidity notice within ninety days after the patent issues.

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Many thanks again for taking the time to meet with Dr. NAIR and me. I respectfully await your decision on which course to pursue.

With my very best regards,

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Mbc:mp

Cc: Gopakumar NAIR, Ph.D.
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